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The Widespread Use of Biotechnology in Italy

Report Categories:

Biotechnology

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Report Highlights:

The average Italian regularly uses products such as insulin and cosmetics that are manufactured using biotechnology. Italy has a large and profitable biotech industry operating in the medical, industrial, and agricultural sectors. Italians generally support the medical and industrial applications of biotechnology more than agricultural biotechnology, and this inconsistency of support across sectors is problematic. Italy is losing an important opportunity to modernize its agricultural production

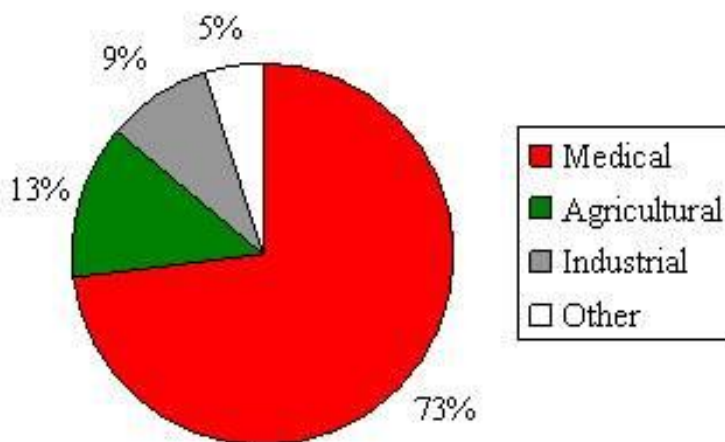
General Information:

Overview

Biotechnology is a common part of life. Italians, however divided they are over agricultural biotechnology, already use and consume a range of biotech products. In 2009 Italy's biotech

industry reported revenue of €5.4 billion. Biotechnology is simply the use of living organisms to make useful products, whether by using intact organisms like yeasts and bacteria, or natural substances from organisms, such as enzymes. There are three types of biotechnology: medical, industrial, and agricultural. Graph 1 shows the distribution of biotech production among the medical, industrial, and agricultural sectors in Italy.

Graph 1. Biotech Production in Italy, by Sector

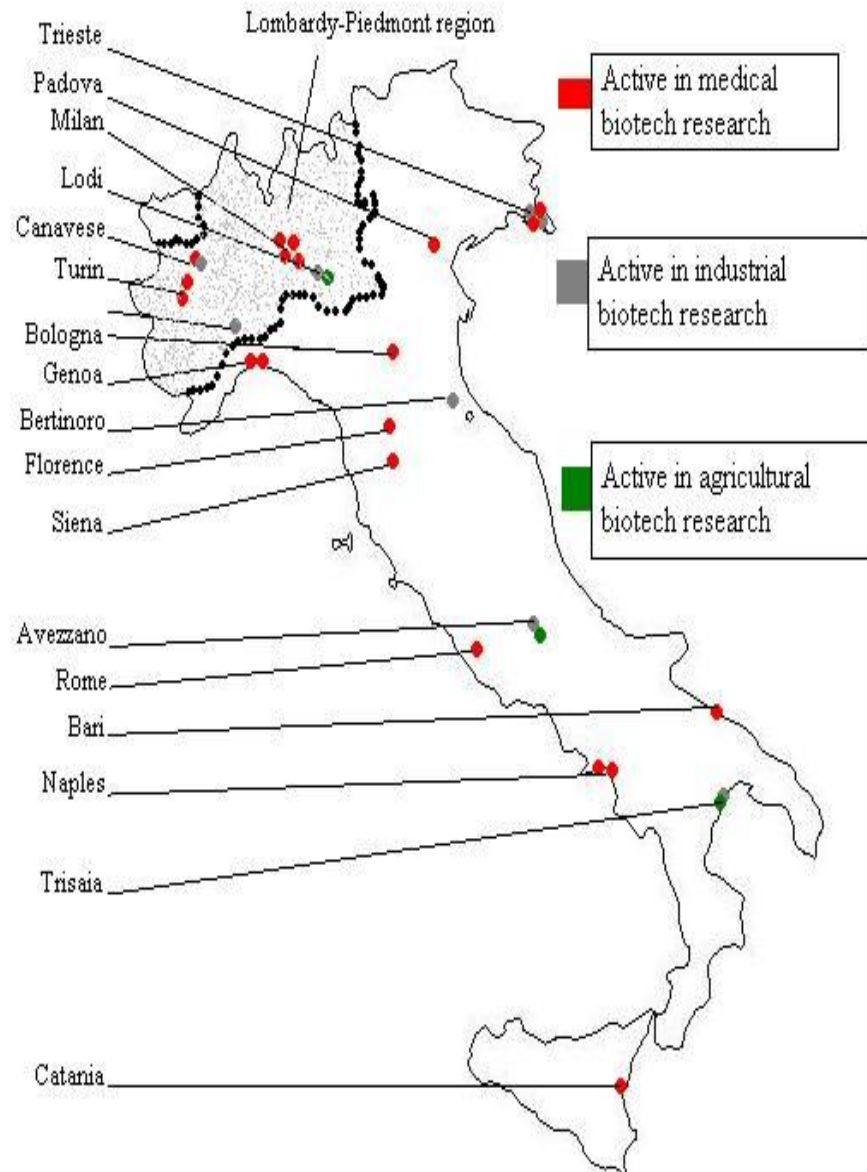


Source: Assobiotec

The number of biotech companies in Italy increased 60% from 1998 to 2005. In 2006 there were 146 Italian biotech companies operating in the three sectors, with 75 dedicated exclusively to research and development (R&D) in biotechnology. Recent figures indicate that as many as 260 companies currently operate in the Italian biotech sector. Most of these companies are fairly small. More than 80% of all Italian biotech companies have fewer than 250 employees and sales below €27 million per year, while 64% of all Italian biotech companies have fewer than 50 employees.

A majority of 70% of Italian biotech companies are located in the north, with the remaining 14% and 16% located in central and southern Italy, respectively. About 80% of all biotech organizations in Italy, including companies, national science parks, and research centers, are located in the north. The Lombardy-Piedmont region alone has 50% of biotech companies and 70% of employees. Map 1 shows the distribution of Italy's primary biotech research institutions, as listed in Appendices 1 and 2.

Map 1. Distribution of Major Biotech Research Institutions



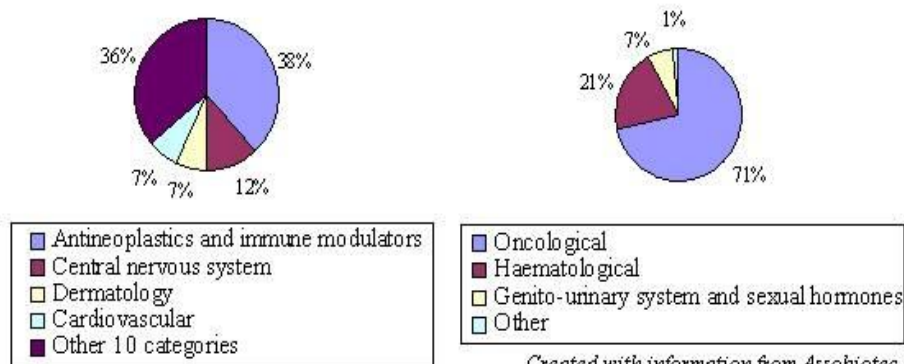
Medical Biotechnology

Medical biotechnology refers to medicinal and diagnostic products or vaccines that consist of, or have been produced in, living organisms and may be manufactured through recombinant technology. [1] It is the most common of the three sectors, both globally and in Italy. With medical biotechnology, human proteins, enzymes, antibodies, and other substances naturally produced in the human body, as well as other living organisms - plant and animal cells, bacteria, viruses, and yeasts - are artificially produced on a large-scale to create innovative medicines.

Insulin is an important biotech product for Italy and an illustrative example of how biotechnology is used to create pharmaceuticals. Using recombinant DNA technology, scientists isolate the human insulin protein and insert that gene into an *E. coli* bacterial cell. The bacteria then multiply to produce synthetic insulin on a large scale, chemically identical to human insulin. Biotech insulin was the first biopharmaceutical to reach the market and has been used since 1982. Almost all insulin in the EU is currently produced through biotechnology due to safety concerns about animal insulin. Italy is the sixth largest market for insulin within the EU, with revenues of €109 million in 2005.

Biotechnology has a range of applications in cancer research, pharmaceuticals, vaccines, stem cell research, genetic testing, genomics, proteomics, pharmacogenomics, and gene therapy. Biotech medicines are used to treat or prevent heart attacks, stroke, multiple sclerosis, breast cancer, cystic fibrosis, leukemia, hepatitis, diabetes, and other diseases. Biotechnology has been used to develop medicines and vaccines for more than 100 diseases, more than half of which are used to treat cancer. Graph 2 shows the distribution of different types of therapeutic biotech products being developed, while Graph 3 shows the distribution of different types of diagnostic biotech products being developed.

Graph 2. Therapeutic Biotech Products **Graph 3. Diagnostic Biotech Products**
Currently Being Developed, by Category **Currently Being Developed, by Category**



Cancer research and treatment is a principle area for medical biotechnology. Italy is the fourth largest market in the EU for cancer treatment, accounting for 12% of total expenditure on cancer treatments and 19% of cancer diagnostics in the EU. Forty of the 258 pharmaceutical products currently being developed in Italy are related to cancer treatment and are in advanced stages of clinical development. As shown in Graph 3, more than 70% of diagnostic biotech products currently being developed are for cancer.

Biotechnology has also been instrumental for diagnosing and treating HIV. HIV diagnostics is an important and profitable industry. UNAIDS estimates that there are 150,000 people living with HIV in Italy, more than in any other Western or Central European country. French-owned BioMerieux has a 5.5% market share of HIV diagnostics in Europe, production sites in France, Italy, and the Netherlands, and annual revenue of €866 million.

Biotech medicines account for 9% of EU pharmaceuticals. The development of new pharmaceuticals is increasingly focused on biotechnology, with growth in biopharmaceuticals twice as high as in non-biotech pharmaceuticals. There are currently 258 pharmaceutical products in pre-clinical, clinical, and advanced research stages of development in Italy, the result of work by 48 companies.

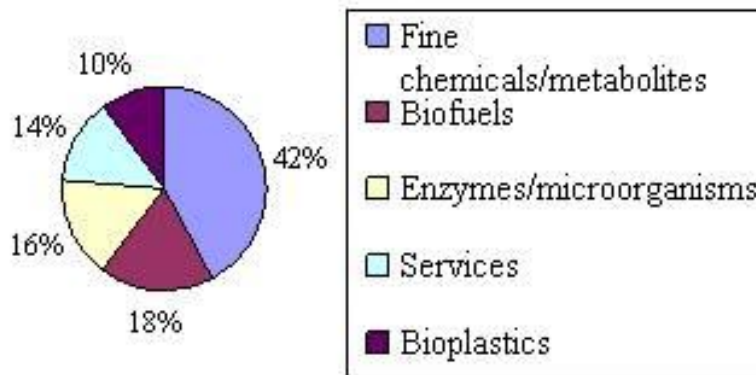
Italy has an average number of clinical trials for all kinds of medical biotechnology compared to other countries in the EU, including for experimental therapies. In December 2007, there were 14 bio-therapies in clinical trials in Italy, of which four were experimental. Italy ranked below the UK, Germany, Denmark, and France, but above the Netherlands, Austria, Sweden, Belgium, Ireland, Finland, and Spain for most clinical trials. Per capita, however, Italy's use of approved and experimental medical biotech clinical trials is lower than almost all major European countries except Spain.

Genetic testing is a relatively new tool in diagnostic medicine, and Italy is one of 13 EU countries that specifically regulate genetic counseling. Italy has professional guidelines on genetic counseling, which the majority of Italians believe are necessary and good to have. There are generally applied practices related to genetic counseling for some situations, and the principle of informed consent is required in all cases. The prevalence of organizations for genetic counseling varies throughout Italy, and future developments in genetic counseling are expected to vary by region.

Industrial Biotechnology

Industrial biotechnology is the use of enzymes and micro-organisms to produce chemicals, materials, and energy. Many common consumer products are produced through biotechnology, such as ethanol, food additives and supplements, colorants, flavors, vitamins, nutraceuticals, cosmetics, pesticides, solvents, and enzymes. Industrial biotechnology has many benefits. It can provide new products and services at lower costs than conventional production. It has the potential to make industrial processes more environmentally friendly by reducing water consumption, reducing energy consumption, generating little or no waste, and reducing CO₂ emissions. Graph 4 shows the share different products have within the industrial biotechnology sector.

**Graph 4. Industrial Biotechnology in Italy,
Share of Total Production**



Derived from IT-SusChem

Laundry detergent is an illustrative example of how biotechnology is used to create industrial products. Detergents include enzymes that break down protein-based stains like egg, milk, or blood. Natural enzymes are ineffective, however, when combined with bleach. Using recombinant DNA technology, scientists changed the protein structure of a natural enzyme by replacing one amino acid with another to create a new bleach-resistant enzyme. Thanks to modern biotechnology, manufacturers now offer consumers laundry detergent that can be used with bleach. Other enzymes are designed to work in cold water without sacrificing cleanliness, creating electricity savings of 30%. A third of biotech enzymes are used in the detergents sector, and the global enzyme market is worth about €2 billion.

Fine chemicals are the largest segment within Italy's industrial biotechnology sector. Chemical production in Italy reached €55 billion in 2006 with exports worth €21 billion. With a 12% market share, Italy is the fourth largest chemical producer in Europe. While not all chemical production involves biotechnology, this is a valuable sector of the economy that will increasingly involve innovative techniques. McKinsey & Company predict that by 2010 bio-based products will account for 10% of chemical sales. Fine chemical production in the EU may become 60% biotech by 2010, driven mainly by increasing biopharmaceutical production.

According to the Italian IB Section of the Technology Platform for Sustainable Chemistry (IT-SusChem), around 50 companies operate in the industrial biotech sector. The largest include Novamont, ENI, and Mossi & Ghisolfi. In 2006, IT-SusChem found that there are 130 large industrial biotech projects on-going in Italy, involving more than 40 different universities, the National Research Council, the National Agency for New Technologies (ENEA), the Ministry of Environment, and

others.

Agricultural Biotechnology

Agricultural biotechnology includes a range of techniques used to breed improved crops and livestock, the most well-known of which is genetic modification (recombinant DNA technology). Examples include *Bt* corn that includes a gene to make the crop resistant to the European corn borer, improved yeasts for better fermentation, and animal vaccines.

The European Commission has approved several biotech crops for cultivation and consumption in the EU. [2] Nevertheless, Italy's Ministry of Agriculture remains staunchly opposed to agricultural biotechnology and has maintained a ban on cultivating biotech crops for the past ten years. The Ministry of Agriculture controls registration of seed varieties and maintains the lowest possible tolerance level for adventitious presence of biotech seed. The Ministries of Agriculture, Health, and Environment control Italy's biotech policy, and each minister has essentially held veto power over biotech approval since 2003. [3] The Ministry of Environment became pro-biotechnology when the Minister of Environment changed in 2007, but the Italian government does not hold a unified position on biotechnology. Its failure to allow biotech cultivation is a major set back for Italy's agriculture industry.

There is pending legislation to restart biotech field trials in Italy, currently approved by the Ministries of Environment and Health, but unapproved by the Ministry of Agriculture. There are nine proposed protocols covering kiwis, citrus, sweet cherries, strawberries, corn, eggplant, olives, tomatoes, and grapes. The decree would give regions the authority to develop their own regulations. Although most Italian regions have declared themselves to be "GM-free," some regions appear open to biotech trials, including Lombardy, Veneto, and Emilia-Romagna – all located in northern Italy.

Despite Italy's ban on biotech field trials, many Italian companies are developing biotech plant varieties able to resist pests or enhance growth during drought or low-nutrient soil conditions. In the future, agricultural biotechnology could also lead to a new generation of crops designed to improve biofuel production. Even though these varieties cannot yet be cultivated in Italy, there are a variety of indirect ways that Italian agriculture already uses biotechnology.

The majority of internationally traded feedstock is produced through biotechnology. The United States, Brazil, and Argentina – three primary producers of biotech soybeans – produce almost 90% of global soybean exports. The EU is highly dependent on imported feed for its livestock industry, and

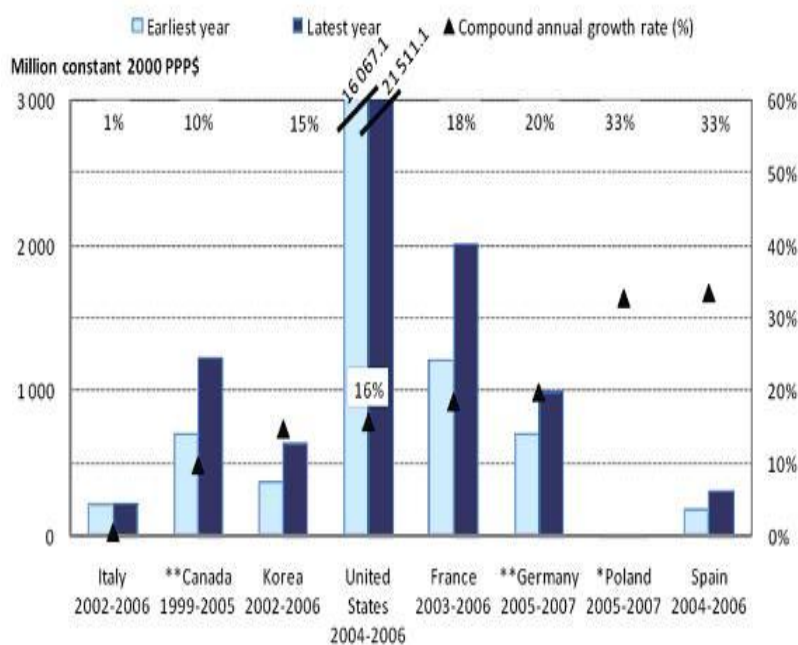
sources estimate that more than 80% of EU soybean meal imports are biotech. Italy's livestock, dairy, and poultry sectors are dependent on imported biotech feed to produce a range of products from Parma ham to Parmesan cheese.

Biotechnology has a variety of agricultural applications beyond field planting and feed for livestock, and Italian firms are active in this sector. For example, biotechnology is used to foster plant health by diagnosing viruses in grapevines, fruit trees, vegetables, and other plants. Italian firms produce biotech chemical fertilizers that are used both in Italy and abroad, and many of the vaccines and pharmaceuticals used to maintain animal health are produced through biotechnology. Fermentation often uses biotech-enhanced brewing and baking yeasts to produce a range of products such as yogurt, cheese, liquor, and wine.

Biotech R&D

Italy's business sector spent €1.5 billion on biotech R&D in 2009, a 15% increase from the previous year. Biotech R&D accounts for about 3% of total R&D funds. From 2002 to 2006 the number of firms engaged in biotech R&D decreased by 1%, but the value of sales at biotech R&D firms increased from \$1.37 billion to \$1.55 billion during the same period. In 2009 there were 41,000 employees in biotech R&D firms in Italy, a 36% increase from the previous year. Italy spent significantly less on biotech R&D than most other OECD countries in 2006, but the average Italian company engaged in the sector spent only slightly less than firms in Germany and other European countries. Italy spent \$249 million on biotech R&D in 2006 compared to \$25.1 billion in the United States, \$2.4 billion in France, and \$1.2 billion in Germany. Each dedicated biotech firm in Italy spent \$2.3 million in 2006, compared to \$7.9 million in the United States, \$4.6 million in France, and \$2.4 million in Germany. Spending on biotech R&D in Italy increased 1% annually from 2002 to 2006, but it increased significantly more in all major competitors, including Canada, Korea, the United States, France, Germany, and Spain. Graph 5 compares the growth of Italy's spending on biotech R&D to that of its major competitors. In addition to being outspent by other OECD countries, Italy also stands to be overtaken by R&D in developing countries such as India and China.

Graph 5. Growth in Biotech R&D Spending, by Country



*Graph taken from *OECD Biotechnology Statistics 2009* report.

The majority of funding for biotech R&D comes from the Italian Ministry for Education, University, and Research (MIUR) and related industry. There are also regional funding programs to encourage R&D. Lombardy has the MetaDistretto Biotechnologico Initiative, Bioiniziative, and others. Piedmont has the Bioindustry Park Initiative, the Bioincubation/Discovery Initiative, and others. Veneto-Friuli has the Nanotechnology District, while Campania and Apulia have the Biopoles Initiative. An important incentive for private biotech R&D funding is the Italian government's 2008 Financial Law. From 2007 to 2009, the government granted a tax credit of 10% for in-house R&D expenditures. The 2008 Financial Law also increased the existing tax credit for R&D investments in partnership with universities throughout Europe from 15% to 40%, with a ceiling of €50 million annually.

Public funding has supported most industrial biotech projects, available through the Ministry of Education, Universities, and Research, the Ministry of Economic Development, the Ministry of Agriculture, and the Ministry of Environment. Local institutions and the European Union have also provided funding. The Ministry of Economic Development has funded the "Industria 2015" program since the end of 2007, through which small and large companies make proposals for R&D related to biofuel production, fine chemical and biomaterial production, and agro-food byproducts and waste valorization. The program has a budget of about €500 million. Of all proposals for funding under the

“Industria 2015” program, 10% are in the field of industrial biotechnology. In 2007 the Italian government significantly increased its budget to \$13.5 million for biofuels R&D, from \$2.4 million in 2006.

There are no special regulations that support the development of bio-based industrial products in Italy, nor are there additional labeling requirements, certification systems, or standardization schemes in place. Italy has exceptionally strong R&D programs in three particular areas of industrial biotechnology:

1. The development of new fine chemicals for the pharmaceutical, chemical, and food industries, as well as of vitamins, proteins, and organic acids from simple and complex substrate mixtures, and some agroindustrial by-products, wastes, and wastewaters;
2. Recovery and characterization of biomolecules (antioxidants, vitamins, etc.) from agroindustry and food-industry by-products, wastes, and wastewaters; and
3. Biotransformation of main components of agroindustry and food-industry by-products, wastes, and wastewaters into flavours, biopolymers, biosurfactants, enzymes, and/or biofuels, such as biogas, biomethane, and biodiesel.

There are two particular weaknesses in the sector:

1. Insufficient knowledge and expertise in biotransformation of lignocellulosic biomass and agroindustrial by-products;
2. Insufficient knowledge and aptitude in the technology transfer phase of new or improved processes and technologies; and
3. Second generation biofuel.

There are several facilities that exist to demonstrate new technologies, test new feed-stock, and examine new pre-treatment processes. For example, the R&D Center of ENEA is a public agency in Trisaia that undertakes R&D in a variety of sectors, including agricultural biotechnology, renewable energy sources (biomass and solar energy), environmental monitoring, waste treatment, and others. Appendix 2 includes an extended list of research centers involved in industrial biotechnology.

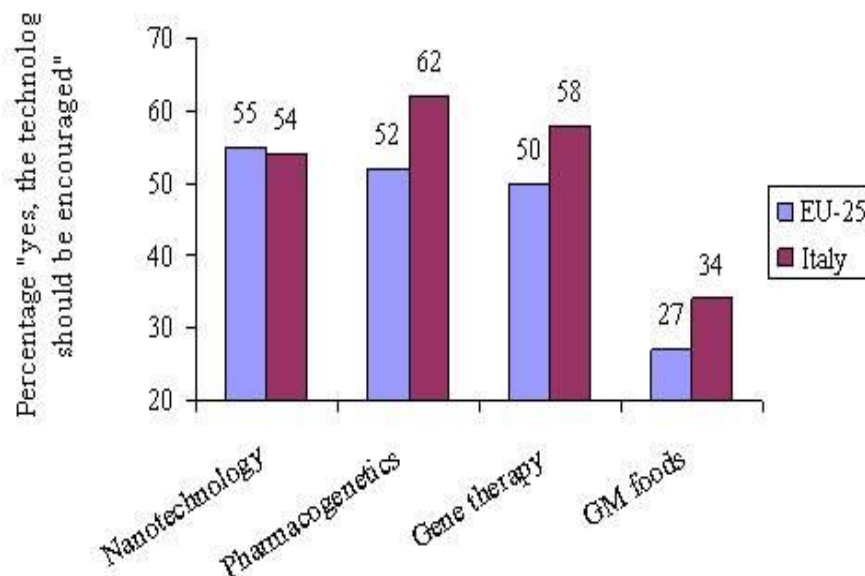
Public Opinion [4]

Like most Europeans, Italians are generally more familiar with agricultural biotechnology than medical or industrial biotechnology. Despite being less familiar with biotechnology’s medical and industrial applications, Italians are far more likely to support its non-agricultural uses, such as the production of

bio-fuels, bio-plants for pharmaceutical production, stem cell research, and genetic testing. There is no clear or scientific explanation for why consumers would support the application of biotechnology in some sectors but not in others.

Italians are generally more in favor than other Europeans of most types of biotechnology, particularly pharmacogenetics, gene therapy, and biotech food. Graph 6 compares responses in Italy and the EU-25 about whether different technologies should be encouraged.

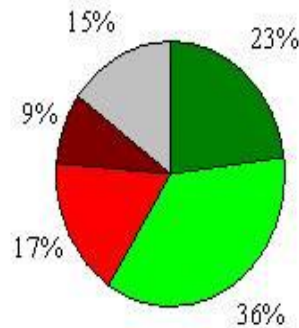
Graph 6. Support for biotechnologies in Italy and the EU



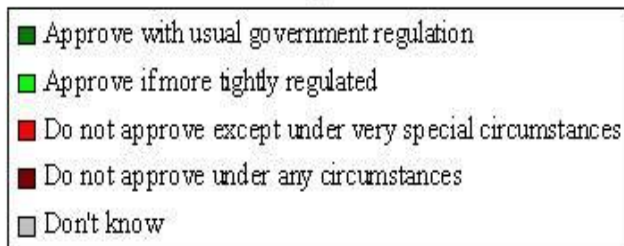
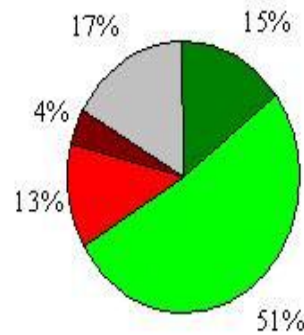
*Graph taken from *OECD Biotechnology Statistics 2009* report.

While Italians are generally equally or more approving of biotechnology than other Europeans, they are also more cautious. One example is public opinion towards stem cell research, a use of biotechnology that is allowed and performed in Italy. Italy has the highest approval among EU countries for embryonic stem cell research (79%) and the third-highest for non-embryonic stem cell research (82%), but Italians are more cautious in their approval and prefer tighter regulation than other Europeans. Graphs 7 and 8 compare EU and Italian responses.

Graph 7. EU approval for stem cell research

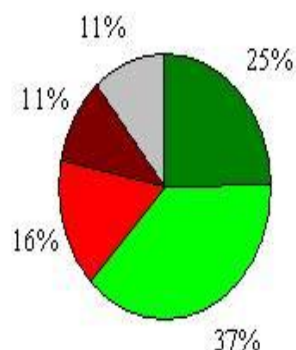


Graph 8. Italian approval for stem cell research

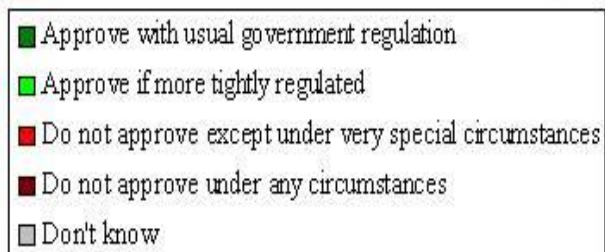
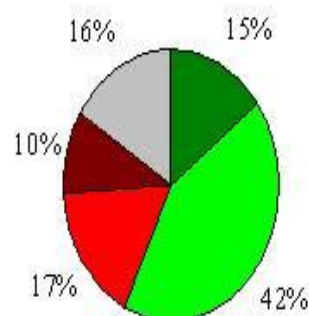


Italian public opinion on growing bio-plants to manufacture medicines and other pharmaceuticals presents a similar case. Opposition is almost identical between the EU and Italy, but Italian supporters are far more cautious than the average European supporter, preferring approval of bio-plants accompanied by tighter regulation. While Italian firms are engaged in bio-plant research, public opinion is more theoretical than tangible because there is no commercial bio-plant manufacturing in the EU. Graph 9 and Graph 10 compare EU and Italian responses.

Graph 9. EU approval for bio-plants



Graph 10. Italian approval for bio-plants



Conclusion

The average Italian regularly uses products such as insulin and cosmetics that are manufactured using biotechnology. Italians generally support the medical and industrial applications of biotechnology more than agricultural biotechnology, and this inconsistency of support across sectors is problematic. Italy is losing an important opportunity to modernize its agricultural production.

Post Contact Information

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Appendix 1. [1] Main Italian Research Institutes for Medical Biotechnology

European Institute of Oncology

Milan

Focus	Clinical and scientific research in cancer treatment, including the development and testing of new drugs.
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Institute for Cancer Research and Treatment (IRCC)

near Turin

Focus	Clinical and scientific research in cancer treatment.
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National Institute for Cancer Research (IST)

Genoa

Focus	Clinical and scientific research in cancer treatment.
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San Raffaele Scientific Institute

Milan

Focus	There are several research wings of the hospital. Relevant departments include the Department of Molecular Biology and Functional Genomics, Viral Immunology Program, Stem Cells Research Institute, Cancer Immunotherapy and Gene Therapy Program, and the Diabetes Research Institute.
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Institute of Molecular Oncology Foundation

Milan

Focus	A non-profit research center dedicated to the study of tumor formation and development.
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CERM Magnetic Resonance Center

Florence

Focus	A research center at the University of Florence, primarily engaged in NMR spectroscopy, i.e. the study of proteins which contributes to pharmaceutical development.
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Immunobiological Research Institute (IRIS)

Siena

Focus	The study of infectious diseases and pharmaceutical development.
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Institute of Neurological Sciences, University of Catania

Catania

Focus	Research and treatment for diseases affecting the nervous system.
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Institute for Bioinformatics in Apulia

Focus	Research in molecular biology through information technology and computer science for medical applications
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CEINGE Institute: Advanced Biotechnology

Naples

Focus	Research in molecular biology and advanced biotechnologies, including applications for treating hereditary diseases, leukemia, and cancer. Other research activities include bioinformatics, developmental genetics, neurosciences, and proteomics.
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National Research Council (CNR)

107 institutes evenly throughout northern, central, and southern Italy

Focus	A variety of research projects ranging from medicine to materials, environment, and communications.
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Universities

More than 70, particularly in Milan, Turin, Padua, Genoa, Bologna, Rome, Naples, and Bari

Appendix 2. Main Italian Research Institutes with a Variety of Activities [2]

R&D Center of ENEA, Trisaia

Public agency

Focus	Multidisciplinary center equipped to perform research and development activities in a wide range of sectors: agro-biotechnology, laser applications, technology innovation for industry, renewable energy sources (biomass and solar energy), metrology, environmental monitoring, radioprotection, rare earths, and waste treatment.
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Contact	Dr. Donato Viggiano E-mail: donato.viggiano@trisaia.enea.it Website: http://www.enea.it/com/ingl/center/Trisaia_Research_Centre.pdf
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Bioindustry Park Canavese SpA, Canavese

Technological park

Focus	This center promotes and develops biotechnological research by hosting enterprises that wish to engage in research and production in chemical, pharmaceutical, diagnostic, veterinary, food, cosmetic, bioengineering, or information science fields.
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Contact	Telephone: +39 0125 561311 Website: http://www.bioindustrypark.edu
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AREA Science Park, Trieste*Technological park*

Focus The key science and technology sectors here are life sciences (biotechnology, biochemistry, biomedical technologies) and physics (nanotechnologies, new materials), as well as electronics and informatics.

Contact Telephone: +39 040 375 5326
Website: <http://www.area.trieste.it>

Park Padano, Lodi*Technological park*

Focus The largest focus is on agricultural biotechnology, with some activity in the industrial biotech sector.

Contact Telephone: +39 0371 4662200 - 46621
Website: <http://en.tecnoparco.org>

CRAB Consortium, Avezzano*Consortium*

Focus Activities include biotechnological products, processes development and optimization, provision of chemical, biochemical, and microbiological analysis in agro-industry, food industry, and the environment. Production of microorganisms, vitamins, and proteins from natural sources.

Services Processes engineering: bioreactors, filtration, chromatographic units, supercritical extraction plant, distillation plant, dehydration plant, centrifugation unit, full milk processing plant, homogenization units, 100 m² clean-room class 100 SED STD. Analytical qualitative and quantitative chemistry and biology laboratories include modern equipment for the characterization of raw materials and bio-transformation products and for the validation of food products.

Contact Website: <http://www.crab.abruzzo.it>
E-mail: segreteria@crab.abruzzo.it

BioSphere SpA, Bertinoro*Private company*

Focus	Biosphere works in industrial biotechnology, and its core business is the development of new fermentation processes for the production of small molecules, intermediates, enzymes, and ingredients. BioSphere offers companies in the pharmaceutical, cosmetic, and agro-food sectors a flexible and customized service for R&D and production. The company's modern and versatile equipment is designed to perform fermentations from lab to pilot and industrial scale, and for the recovery and purification of the products.
Services	The pilot plants and production facility are designed to work with microorganisms up to biosafety level 2 and genetically modified organisms belonging to Class 1, in accordance with EU Council Directive 98/81/EC. The fermentation facility includes fermenters of different sizes, from the laboratory scale (1 and 15 liters) to the pilot (150 liters) and pre-industrial scale (1,500 liters), equipped with temperature, pH, pO ₂ , air, pressure, stirring controls and regulations. The downstream equipment includes centrifugals, microfilters, ultrafilters, reverse osmosis, filter-driers, and bell filters. Chromatography and lyophilisation tests can be performed on a laboratory scale. The chemical and microbiological laboratories are equipped with HPLC, UV-VIS, and FT-IR spectrophotometers for the analysis and identification of components, Atomic Absorption spectrophotometer for metal trace analysis, microscopes, static and orbital incubators.
Contact	Website: http://www.biospherespa.com Chief Operating Officer : Marco Pistocchi E-mail: info@biospherespa.com Telephone : +39 0543 444597

SPRNI Technologies, Trieste

Consortium

Focus	SPRIN is partner of Resindion S.r.l. (Mitsubishi Chemical Corporation), leader in the industrial production of functionalized polymers specific for enzyme immobilization, solid phase synthesis, and chromatography. SPRIN is a spin-off of the Università degli Studi di Trieste.
Services	Services for biocatalysed process development, prediction of thermodynamics of biocatalysed reaction systems, enzyme selectivity, enzyme thermostability, biocatalyst development. Provides support to chemical, pharmaceutical, and food industry in the implementation of sustainable processes.
Contact	Website: http://www.sprntechnologies.com/sprin/ E-mail: info@sprntechnologies.com Phone: +39 040 5583110

^[1] According to Europabio, “Recombinant DNA is a form of DNA that does not exist naturally. It is created by combining DNA sequences that would not normally occur together.”

^[2] Regulation (EC) No 1829/2003, Directive 2001/18/EC

^[3] Legislative Decree 334/2003. For more information see GAIN IT8041.

^[4] This section uses data from Eurobarometer 64.3, *Europeans and Biotechnology in 2005: Patterns and Trends*.

^[5] <http://www.piemontelifesciences.org/documents/biotechinitialyoverview.pdf>

^[6] List taken from *Industrial Biotechnology in Italy*, 2009 Europabio.

^[1] <http://www.piemontelifesciences.org/documents/biotechinitialyoverview.pdf>

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